

U.S. DISTRICT COURT  
DISTRICT OF NEW JERSEY - TRENTON

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ASTRAZENECA AB, et al., : DOCKET NO. CV-11-760 (JAP)  
: :  
Plaintiffs, : Trenton, New Jersey  
: :  
-vs- : Friday, February 1, 2013  
: :  
HANMI USA, et al., :  
: :  
Defendants. :  
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TRANSCRIPT OF TELEPHONE CONFERENCE HEARD BEFORE  
THE HONORABLE TONIANNE J. BONGIOVANNI, U.S.M.J.

TRANSCRIPT ORDERED BY:

McCARTER & ENGLISH, LLP

A P P E A R A N C E S:

(See attached)

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02/01/13

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COURT DECISIONS:

On permitting discovery to AstraZeneca

13

On discovery re Judge Pisano's decision

request to admit

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1 (On record at 02:29:00 p.m.)

2 (All attorneys appearing telephonically)

3 THE COURT: Good afternoon. We're on the record in  
4 AstraZeneca vs. Hanmi, 11-760.

5 And I wanted to stress that we are on the record. I  
6 know that you have submitted documents, letters, arguments and  
7 have indicated that they be confidential, so we'll have to  
8 deal with the transcript and any -- and sealing of the any of  
9 the statements that are made after this hearing.

10 Although we're in the courtroom, there's no one in  
11 here, just me and my Law Clerk. So you have that protection.

12 Anyway, can I have appearances, please, on behalf of  
13 AstraZeneca?

14 MR. FLAHERTY: Yes, Your Honor. From McCarter and  
15 English, this is John Flaherty and Ravin Patel, P-A-T-E-L.  
16 And I'll let my co-Counsel introduce himself.

17 MR. HAUS: Good afternoon, Your Honor. For  
18 Fitzpatrick Calle, also for Plaintiffs, Bruce Haus speaking.  
19 With me is my colleague Joshua Rothman and Einar Stole from  
20 the Covington firm is also on the line.

21 THE COURT: Okay. And then for the Defendant?

22 MS. TARANTINO: Good afternoon, Your Honor. Mayra  
23 Tarantino of Lite, DePalma, Greenberg. And joining me is Mark  
24 Volen (phonetic) from Shagrew (phonetic).

25 THE COURT: Good afternoon.

1 MS. TARANTINO: Good afternoon.

2 THE COURT: You have raised before me two issues and  
3 I'll talk about the first one that involves the patent  
4 information form and the revised form that was submitted.

5 Let me get right to the heart of it and ask  
6 AstraZeneca why the form is relevant at all and more  
7 pointedly, if you can tell me, why Astra has not raised as  
8 direct infringement claims relating to eight and nine? That's  
9 just a curiosity to me.

10 MR. ROTHMAN: Good afternoon, Your Honor, this  
11 Joshua Rothman and I will address those in -- in order.

12 The first question was why is it relevant. The 2010  
13 form that was submitted was Hanmi's statement and  
14 representation to the FDA that their product that they sought  
15 approval to market for a particular invitation infringes  
16 claims eight and nine of the 504 patent. That patent is  
17 attached as Exhibit A to our motion.

18 If you look at claim eight, it reads "a method for  
19 the treatment of gastrointestinal inflammatory diseases,  
20 comprising the oral administration to mammal, including man,  
21 in need of such treatment, a composition comprising an  
22 effective amount" and then it goes on to describe an active  
23 ingredient.

24 The same language that I just read is also present  
25 in asserted claim seven. Therefore their representation that

1       their product infringes those method of treatment limitations  
2       is relevant to the question of whether they infringe those  
3       very same claim limitations in asserted claim seven.

4               And again there is similar language with regard to  
5       claim nine, which is -- which they represented was infringed  
6       in their 2010 statement, because the claim language in claim  
7       nine is similar to language in claim six.

8               So that is why their representation to the FDA that  
9       their product infringes claims eight and nine is relevant to  
10      asserted claims six, seven and ten.

11              THE COURT:   Okay.   And then the second part of my  
12      question?

13              MR. ROTHMAN:   I'm sorry, Your Honor, did you want to  
14      ask a question?

15              THE COURT:   No, no, go ahead.

16              MR. ROTHMAN:   Okay.   So in the second -- the second  
17      question you asked was why did we not assert claims eight and  
18      nine in this litigation.   At the time that we had to decide  
19      which claims to assert, it was AstraZeneca's belief that  
20      Hanmi's product did not infringe on those claims at that time,  
21      based on the information we had.

22              THE COURT:   All right.   But they come -- after 2010,  
23      they come and tell you or tell the FDA and you have access to  
24      this in discovery that -- their assertion that they do in fact  
25      infringe those claims and you've never changed your

1 infringement contentions, right?

2 MR. ROTHMAN: That is -- that is correct. What we  
3 did was we took that 2010 statement and, again based on the  
4 information we had, we did not seek to amend our contentions  
5 to add claims eight and nine and we are not seeking to do that  
6 here. We are not looking to assert claims eight and nine  
7 based on the information we have.

8 What we are seeking is the ability to maintain the  
9 admissions that they made as support for our infringement  
10 contentions concerning claims six, seven and ten. And so  
11 during discovery, we have that 2010 statement which was their  
12 admission made by their lawyer on a declaration to the FDA.

13 And then we took their 30B6 deposition of their  
14 regulatory person. That deposition occurred in November 15th  
15 and 16th of 2012. We asked that regulatory  
16 supervisor/manager, Mr. Quon, whether he had any information  
17 as to whether that 2010 statement was incorrect. Again, he  
18 was the regulatory person. He recognized that this was a  
19 document that was submitted to FDA that he likely would have  
20 reviewed.

21 We asked him whether he had any information as to  
22 whether this document wasn't accurate. In the two years since  
23 that document was filed with the FDA, he had no information  
24 that indicated that document was inaccurate.

25 We also asked Shagrew's Counsel at that deposition

1 whether they would agree that this document was a business  
2 record. We asked that question so that we would insure that  
3 we would be able to rely on this admission at trial. At that  
4 deposition Shagrew's lawyer agreed that the document fell  
5 within the business record exception to hearsay.

6 The deposition ended with AstraZeneca having the  
7 admission from Hanmi's 30B6 supported that the document was  
8 truthful or at the very least non-inaccurate and we had  
9 Shagrew's stipulation or representation that the document was  
10 a business record. So the document is coming into evidence,  
11 too.

12 THE COURT: So essentially you, without alleging  
13 that eight and nine are infringed, you were going to use that  
14 patent information form, from 2010 that Hanmi submitted to the  
15 FDA, as an inference and/or to support your argument that  
16 these other claim terms are therefore infringed, but not --  
17 there would not be direct infringement of eight and nine based  
18 on that statement, but rather you would use it as support for  
19 your arguments that -- which are they, six, seven and ten?

20 MR. ROTHMAN: That's correct, Your Honor.

21 THE COURT: That -- is that --

22 MR. ROTHMAN: That is correct -- that is correct,  
23 Your Honor, and that continues to be our position today.

24 THE COURT: All right.

25 MR. ROTHMAN: I was -- I -- go ahead.



1 THE COURT: No, I am --

2 MR. ROTHMAN: -- your question or did it?

3 THE COURT: -- this is just a unique situation.

4 -- let me turn to Hanmi for a minute. I know that  
5 one of the questions that Astra has asked is whether or not  
6 you intend to rely on the revised form that was propounded to  
7 them on November 30th and authored or at least submitted to  
8 the FDA on November 20th, 2012.

9 MR. VOLLEN: Good afternoon, Your Honor. It's Mark  
10 Vollen for Hanmi. Let me just start by fixing a couple things  
11 that Mr. Rothman said.

12 First of all that first firm from 2010 does not say  
13 anything about infringement of claims eight and nine. That  
14 form is Exhibit C to AstraZeneca's January 9th letter and in  
15 the relevant box, the question asked by ND -- the ND -- the  
16 FDA, excuse me, is whether Hanmi's NBA relates to a product  
17 having relation to a method that's claimed in the 504 patent.

18 And claims eight and nine are not the claims and  
19 those two claims are listed -- were listed there, but that  
20 form said nothing about infringement of the patent.

21 And AstraZeneca knows very well that there is no  
22 infringement, because claims eight and nine relate to a method  
23 of treatment using a specific compound. Okay? And that  
24 compound is different from the compound that's being litigated  
25 in this suit.

1 THE COURT: Okay. Then let me ask why you saw fit  
2 to revise the form?

3 MR. VOLEN: Because in October of this year, or  
4 excuse me of '12, Your Honor, just a few months ago, when  
5 Hanmi submitted some additional papers to the FDA, Hanmi's  
6 agent was advised that the form had to be updated in short  
7 order. Okay?

8 And the day they were due or the day the form was  
9 due, we, meaning my law firm, was advised of this. We took a  
10 look at the form. We noticed that the original one that had  
11 been submitted to you before by Hanmi's prior Counsel didn't  
12 make any sense on the 504 patent, so we took -- we fixed it,  
13 because Hanmi, then --, is not in fact combining a method that's  
14 called for on the claim.

15 Mr. Rothman indicated that after the deposition,  
16 Hanmi's Counsel indicated that these documents are indeed  
17 business records. We don't have a problem with AstraZeneca  
18 using the forms at trial and try to draw whatever inferences  
19 it can from them. But certainly there's no admissions of  
20 infringement and there's no need for any discovery about this,  
21 Your Honor.

22 THE COURT: So I assume in your response that you do  
23 intend to rely upon this revised form?

24 MR. VOLEN: Your Honor, if they introduce the  
25 original form, we know -- we may want to -- to rely on the

1 revised form, so that Judge Pisano has a full understanding of  
2 the relevant facts as it relates to any issue on the case.

3 And just to be clear, they don't relate to  
4 infringement per se, in -- in the terms of the admission that  
5 AstraZeneca is arguing, because the compounds are different.  
6 Eight and nine relates to a different compound. It's the free  
7 base form and claims six, seven and ten relate to a salt form.  
8 And that's what the parties are litigating here is the salt  
9 form claim.

10 THE COURT: No, I'm clear on that. The question is  
11 whether this change in your position, two and a half years  
12 later and after the close of discovery, is now of the  
13 magnitude that the Plaintiff should be entitled to take  
14 discovery on why there was a change.

15 And let me just comment on the timing. I recognize  
16 that Hanmi's position is they followed the rules. I find it  
17 -- what's the proper phrase? It's not quite disingenuous, but  
18 I can't quite have the outrage or the indignation that Hanmi  
19 seems to have regarding Astra's request to have discovery on  
20 this and how you just simply say, without blinking, that  
21 "discovery is closed", when this form just coincidentally is  
22 authored and sent to the FDA on the same day that fact  
23 discovery is closed. You followed the rules and you produced  
24 it, not the same day or the next day, 10 days later, fine.  
25 But to say that therefore Astra should be precluded from

1 taking any discovery because of the timing, just doesn't  
2 resonate with me.

3 I will accept the representation that this form --  
4 there wasn't anything more sinister going on, on Hanmi's part,  
5 because this form was not revised and the decision wasn't made  
6 to revise it until sometime in October, just a month before  
7 the close of fact discovery.

8 If I had any indication that there was an intention  
9 to revise the form in 2011 or early prior 2012 and you folks  
10 sat on this, you'd be in trouble, to put it plainly.

11 But putting that aside, and I don't want Hanmi to be  
12 defensive about that now, we're moving to the substantive  
13 issue of whether or not it warrants discovery.

14 And, Mr. Haus, were you going to comment on the  
15 import of this form?

16 MR. ROTHMAN: Yes -- yes, Your Honor. This Mr.  
17 Rothman speaking.

18 THE COURT: Oh, I'm sorry.

19 MR. ROTHMAN: I did want to respond to Mr. Volen's  
20 representation as to what the form says. I will again direct  
21 you, it is Exhibit C to our motion.

22 THE COURT: Yes, I've read it.

23 MR. ROTHMAN: The document does bear -- the document  
24 does bear Hanmi's Bates numbers. If you have it before you,  
25 it's Hanmi 355. The Section 4.2 on that form, the first box

1 next to that says patent claims number that's listed in the  
2 patent and that is where claims eight and nine are represented  
3 by Hanmi.

4 But if you look at the -- the box right to the right  
5 of that, it reads "does or do the patent claims referenced in  
6 4.2 claim a pending method of use for which approval is being  
7 sought in the pending NBA amendment or supplement?" And the  
8 box is checked "yes".

9 That is Hanmi's representation that claims eight and  
10 nine do claim the indications which are listed right below it  
11 in box 4.2A. So this is a representation by Hanmi that it  
12 believed, when it submitted this form, that claims eight and  
13 nine were infringed by the four indicated it was seeking  
14 approval for.

15 THE COURT: Okay. I understand, folks, that we have  
16 a dispute as to what this means and whether or not it is as  
17 clear as Astra somewhat represents, namely, that you're  
18 conceding infringement of eight and nine.

19 Frankly, what exactly this means -- it's certainly  
20 important in terms of the relevance issue. I can tell you  
21 that I'm comfortable in recognizing that AstraZeneca has all  
22 along been relying upon this form and in fact asked questions  
23 at a deposition regarding the assertions in this form and it's  
24 important to them.

25 Whether or not it's something that Judge Pisano is

1 going to find relevant or admissible, or if there is an  
2 inference that is going to be of any moment in his decision is  
3 for Judge Pisano to decide after he hears argument. But I do  
4 find that this form and the changed form are relevant. And  
5 obviously so does Hanmi to the extent that you're agreeing  
6 that if AstraZeneca is going to rely on the 2010 form, then  
7 there's going to be reliance by Hanmi on the revised 11/30/12  
8 form.

9 So leaving you folks, respectfully, to make your  
10 argument that this form should not be considered or should be  
11 considered for another day, the question that I have is  
12 whether or not AstraZeneca is entitled to some discovery and I  
13 find that they are.

14 The scope of that discovery, however, is not going  
15 to be as broad as AstraZeneca would like. Perhaps the best  
16 way -- place to start is for the -- Mr. Volen, for your client  
17 to review the additional papers that were submitted to the FDA  
18 in 2012 and if they are the documents that were instrumental  
19 in prompting this revision, then they should be produced or a  
20 privilege log should be produced.

21 And, in any event, I will allow a deposition as to  
22 why it was determined that this form should be altered and  
23 whether we go back to that regulatory individual or someone  
24 else who could talk about why it was tweaked and changed and  
25 fairly significantly is to be decided by the parties.

1           So that's where I come down on that issue. Any  
2           questions. I'm looking to have the scope and the discovery  
3           very narrow and given the time frame that we're talking about,  
4           that's been represented to me, from October through November,  
5           we shouldn't be looking at a wealth of documents that would be  
6           implicated.

7           I'm not allowing --

8           UNKNOWN: Your Honor --

9           THE COURT: Let me just finish and then I can  
10          certainly hear from you. I'm not wrapping up into this  
11          discovery what prompted the 2010 assertion or why that form  
12          said what it says. It's been represented that it's a business  
13          record, you can use it. It does say what it says.

14          And you can go through all of the steps that were  
15          taken by the parties before that was put together and sent to  
16          the FDA, but I'm not going to have you look at supporting  
17          documents for that or pepper anyone with questions re-opening  
18          a deposition solely on why the form was changed. And I say  
19          that rather simply, knowing it's probably not so simple and  
20          I'll be hearing from you.

21          I need to keep you on a tight schedule, so I will  
22          let you folks confer and come up with a game plan and let me  
23          know early next week what the game plan is for the production,  
24          so that we're not affecting trial or expert reports or the  
25          like.

1           Okay, who wants to go first? Mr. Rothman, were you  
2           about to speak?

3           MR. ROTHMAN: This is Joshua Rothman for the  
4           Plaintiffs.

5           THE COURT: Yes.

6           MR. ROTHMAN: I would like to just raise one issue.  
7           I think it wasn't -- he did allude to the importance of it  
8           earlier when you were speaking about how you would be upset if  
9           Hanmi did in fact know about the inaccuracy of the form in  
10          2011 and did not change it then, but rather waited until now.

11          I would just ask if you would ask Hanmi to represent  
12          that in fact they were not aware of this inaccuracy in 2012.  
13          They have not made that representation and frankly we believe  
14          they did know about it as early as 2011 and did withhold it  
15          until now.

16          I understand you don't want to disparage them in any  
17          way and so therefore I would just ask you to ask Mr. Volen to  
18          make the representation on the record that should -- Hanmi was  
19          not aware of this inaccuracy until late October 2012.

20          THE COURT: Mr. Volen?

21          MR. VOLLEN: Yes, Your Honor, it's Mark Volen. Yeah,  
22          I would like to know why this allegation and this theory of  
23          infringement based on Mr. Rothman's alleged -- alleged  
24          admission in that form was never in AstraZeneca's infringement  
25          contention regarding claims six, seven and ten?



1 And if they knew about it from the time they had  
2 that document, since April of 2010, why was it not part of the  
3 contention? And we put that in our letter to Your Honor.

4 THE COURT: I understand that. I understand, Mr.  
5 Volen, and it's great that, what is it, a good defense is a  
6 good offense? It doesn't work with me here. AstraZeneca has  
7 clearly through the discovery process indicated that this form  
8 was important to them. There's been no arguments that they  
9 shouldn't get it or that it isn't relevant.

10 So by allowing it to be produced and allowing it to  
11 be recognized as a business record and allowing AstraZeneca to  
12 ask questions about it clearly places its relevance -- makes  
13 its relevance a non-issue at this late stage.

14 AstraZeneca has represented that they are not  
15 asserting eight and nine are infringed. How much traction, if  
16 you will, they're going to get from the argument that there is  
17 this inference is again for another day.

18 But I am sitting here hearing that it's important to  
19 them and you obviously view that it's important enough to need  
20 to keep the record accurate and somebody looked at this 2010  
21 form and said, ut oh, we need to make changes. And now we're  
22 getting this at the -- really after the close of fact  
23 discovery.

24 So I don't feel that there is any need to ask  
25 AstraZeneca why not, because it has been recognized as being

1 relevant. It's not their position regarding eight and nine.  
2 If you want to challenge their expert at trial, you can  
3 certainly do that.

4 So the question that I would like answered, and  
5 whether you need to confer with your client, is I would like  
6 to know when it was determined that this form needed to be  
7 changed. And what I -- I believe I heard from you is that  
8 something happened in October 2012 where additional papers  
9 were being submitted to the FDA and you were told by the FDA  
10 that you needed to update your documents in short order and  
11 then the form -- it was decided that the form was going to be  
12 amended.

13 So if you can't represent to me that that's what  
14 happened or I'll put it this way, if there's any indication  
15 that Hanmi knew they were going to be revising this form, but  
16 you waited, I want to know about it.

17 MR. VOLEN: That is absolutely nothing that. As I  
18 said previously, on October 29th of last year, Hanmi submitted  
19 amendments to its NBA with the FDA who subsequently notified  
20 that these forms had to be updated. That information came  
21 from my law firm in early November. And within a day or so we  
22 looked at the forms, turned them around.

23 My colleague, Ms. Lee, signed off on the final  
24 forms, gave them back to the agents. They were submitted to  
25 the FDA. We viewed it as a ministerial correction of that

1 one paper. It was produced to AZ promptly, okay, along with  
2 all the other submissions to the FDA. We're required by the  
3 rules to produce the ongoing correspondence and we've been  
4 doing that -- finished or here.

5 THE COURT: Okay. I --

6 MR. VOLEN: Whether Hanmi ever knew about it before  
7 that, they never told me or anybody in my firm. That's all I  
8 can say.

9 THE COURT: All right, Mr. Volen. I will leave that  
10 issue there and as I said, I'd like you to take a look at the  
11 forms that were reviewed and prompted the ministerial  
12 correction, as you characterize it, and let us know if they  
13 can be produced. If for some reason you have a privilege,  
14 then you need to provide the Plaintiff with a log.

15 And not knowing the volume of documents or how long  
16 this would take, I would just like some feedback from you  
17 folks next week. Just an e-mail would be fine saying here's  
18 our game plan.

19 I don't want anyone sitting on this or, if there are  
20 going to be more issues that are raised with me, I need to  
21 make sure that we all have time to deal with them, because  
22 that 30-month day is looming, as you all know. You know  
23 better than me and I don't want to cause a log jam for you in  
24 getting ready for trial and what the spill over effect might  
25 be. Okay?

1 I'd like to switch --

2 MR. VOLLEN: --

3 THE COURT: Yeah.

4 MR. VOLLEN: -- sorry. Can I raise one last point?

5 If there's going to be deposition on the -- could we ask that  
6 it be ordered to occur in Korea? The business folks at Hanmi  
7 are always very good. During the depositions that did occur  
8 during fact discovery, this is a routine that if somebody  
9 needed to be deposed, it was a week out of their business --.

10 -- date -- the prep time, ready for a deposition,  
11 translation and so on.

12 THE COURT: I will certainly consider options. I  
13 don't want to rule in a vacuum and here's why. I'm not sure  
14 who the correct person to depose would be and I will give  
15 Hanmi the opportunity to offer someone.

16 And as an example, I recognize that we don't  
17 generally want to expose trial counsel to depositions, but if  
18 this is Miss Lee or there is anyone else who is in the United  
19 States who has reviewed the documents and could be the  
20 appropriate person, I'll leave you to discuss that and then  
21 let me know if you have an issue as to who that should be.  
22 And then if it's someone who is in Korea, discuss how that  
23 should take place.

24 The other option is also, if it is someone who is in  
25 Korea, that the deposition could be conducted by video

1 conference.

2 I don't expect this deposition to necessarily be  
3 very lengthy, but again I'm talking about this in a vacuum.  
4 You folks -- certainly Hanmi is in a better position to know  
5 which documents were reviewed and anticipate what your  
6 testimony is likely to cover. AstraZeneca is a bit more in  
7 the dark and I am certainly more in the dark than either of  
8 you on this issue.

9 So a long winded way of suggesting that we go  
10 through the document exchange first and you folks have a  
11 discussion over who the appropriate person should be with  
12 Hanmi making an offer if you want. Okay?

13 MR. VOLEN: Thank you, Your Honor.

14 THE COURT: All right. Switching to the request to  
15 admit. Just somewhat as an aside, I found it interesting, if  
16 that's the proper word, as to why Astra needed to know whether  
17 or not Hanmi would agree that all humans are mammals. Never  
18 seen one like that. And then on the other side, Hanmi refuses  
19 to answer that.

20 So that's how I enter this discussion and that is  
21 something that I could use as a prime example of why, although  
22 I understand the benefit of requests to admit, they are often  
23 more trouble than they're worth. And yes, I am on the record  
24 saying that.

25 Okay, stepping back. I think both sides are a

1 little bit correct as to what my thoughts were regarding this  
2 discovery. I never ruled definitively that we were going to  
3 extend discovery. I left open the possibility that, depending  
4 on how claim construction came down, as well as the Motion to  
5 Amend contentions, that you might not be done. And I wanted  
6 you to go off and see if you could reach an agreement as to  
7 the game plan going forward, meaning, a schedule.

8 I also had encouraged you to have a discussion over  
9 what discovery might be conducted, even though Hanmi was  
10 opining that there really wasn't a necessity for any  
11 discovery.

12 And the reason I threw that out there is frankly  
13 that has worked in other situations where parties might agree  
14 that it is more expeditious to conduct the discovery that's  
15 being requested instead of fighting about it. So I sent you  
16 with that hope, if you will, in mind.

17 Where I come down now that we have a ruling by Judge  
18 Pisano that was entered on the docket on the 23rd, just a week  
19 ago, is that I'm going to permit discovery into the  
20 information that has been permitted by Judge Pisano, meaning  
21 that Hanmi should be permitted to assert that its proposed  
22 product does not infringe, because the claims do not encompass  
23 hydrated forms of the claimed salt of esomeprazole. And  
24 that's found on page three, the last sentence on page three of  
25 Judge Pisano's opinion.

1           So to the extent that the permitted amendment ruled  
2       upon by Judge Pisano warrants discovery, I'm going to allow  
3       that. I should add I am anticipating that it should be very  
4       discreet and very limited. This isn't an opportunity to open  
5       the flood gates.

6           In terms of the request to admit, I don't see them  
7       being helpful in this case and by that I'm not at all faulting  
8       AstraZeneca for trying. That is what I think you need to do  
9       and at some point you folks are going to have to focus on  
10      information that you can stipulate to for trial purposes and  
11      that's right around the corner.

12          But I am concerned that Hanmi's responses are only  
13      going to open up the flood gates and that you're going to  
14      spend a lot of time briefing specifically why you can't  
15      respond to each of these requests.

16          So instead of dealing with the request to admit, I  
17      think you folks should start working on your stipulations.  
18      And let me caution you, you don't want to be trying this case  
19      in front of Judge Pisano or any District Judge where you  
20      haven't pared down only to the essentials what's going to be  
21      at issue. It's just a waste of everyone's time.

22          So if you want to use as a template the requests to  
23      admit and figure out how you can formulate your stipulations,  
24      then go ahead and do that.

25          So coming full circle, I'm not going to require that

1 Hanmi respond to all of the requests to admit. I am going to  
2 permit discovery on the amended contentions as incorporated  
3 into Judge Pisano's opinion, which is document 269 of our  
4 docket, which was entered on January 23rd, as I mentioned.  
5 And you folks should go off and talk about the scope and if  
6 you have issues as to what that means, then that's something  
7 that I -- I will have to address.

8 Any questions from Plaintiff?

9 MR. HAUS: Your Honor, this is Bruce Haus. No  
10 questions. And I understand your order. I would like to  
11 point out however that expert reports, based upon the schedule  
12 we've agreed to, are now due on February 19th.

13 Unfortunately the claims of the patents are -- they  
14 say what they say and one of them says that a human is a  
15 mammal and we wouldn't have thought that was a difficult issue  
16 to get an admission on for example, but without those  
17 admissions we will now be required to have our experts put in  
18 their reports all these little details that we were hoping to  
19 avoid.

20 We certainly can do that and we can work on  
21 stipulations, but if the past experience we've had in trying  
22 to get simple things like this from Hanmi continues, it may be  
23 a little difficult, but we certainly understand and we will  
24 proceed as you have ordered.

25 THE COURT: Okay. Let me do this. This I might be



1       able to help you with. In light of the -- well, before I  
2       rule, Mr. Haus, do you know if there's going to be a problem  
3       with your producing the expert report on that date because of  
4       the discovery you'd be getting on -- or be seeking on the  
5       amended contentions?

6               MR. HAUS: Well, to be honest, Your Honor, the  
7       possibility exists, because we're still not sure of the claim  
8       term that needs to be construed, if any, with respect to the  
9       issue of hydrates. We believe that there is a claim term with  
10      respect to that, that is still disputed. However Hanmi  
11      disagrees.

12             We will certainly learn more during the expert  
13      phase, but unfortunately these expert reports will be very  
14      difficult to write and to respond to, because in many cases  
15      we'll be writing things that may be unnecessary. The experts  
16      will be giving opinions on things that may be unnecessary and  
17      we were hoping to limit those things in part through --  
18      through things like these requests for admissions that in all  
19      honesty could have been answered a month ago quite easily,  
20      despite the -- the number.

21             Hanmi could have answered those in far less time  
22      than we spent on these motion papers and we wouldn't be  
23      talking to Your Honor on this issue.

24             However it appears that that is not possible and  
25      we're just going to have to go into our expert phase a little

1 bit in the dark.

2 THE COURT: All right. But --

3 MR. VOLLEN: Your Honor, it's Mark Vollen.

4 THE COURT: Yes.

5 MR. VOLLEN: Mark Vollen. Could I speak -- because I  
6 think that this -- if the Judge's ruling here is really, you  
7 know, while it has permitted the proposed amendment, has made  
8 -- stated on those motion papers, they were essentially  
9 amendments which conformed the position to the records that  
10 have been taken during discovery and include a summary  
11 judgment record.

12 And so, as Judge Pisano said, -- is --. Hanmi is  
13 not permitted to assert non-infringement based on the hydrates  
14 distinction. The only question is whether or not the claims  
15 cover hydrates, yes or no. It's -- there's no dispute that  
16 Hanmi's product is a petrol hydrate. It's been established by  
17 AstraZeneca during discovery.

18 And so we frankly don't see what discovery is  
19 necessary.

20 THE COURT: So your position is that all that has  
21 been touched by the opinion is adding the new claim of  
22 infringement and so no new discovery is warranted?

23 MR. VOLLEN: Yes, we -- our -- our position, to the  
24 extent it's based on non-infringement, is based on the  
25 position that AstraZeneca has taken on the record primarily.

1 I think the claims, on the other hand, do cover the hydrates.  
2 Judge Pisano made clear that our invalidity defense is a  
3 bit --, certainly all matters for the expert reports that are  
4 coming up in this case.

5 But honestly the only question that's -- simply the  
6 only issue that is out there from a factual standpoint is the  
7 composition of Hanmi's products as to which AstraZeneca has  
8 had plenty of discovery.

9 I don't know, Your Honor, if you, by your comments,  
10 you were thinking that, you know, discovery is re-opened or  
11 something on Hanmi's product, but with due respect, we don't  
12 think there's any need. We're happy to try to work out  
13 stipulations with Mr. Haus and his team.

14 THE COURT: Well, two things. One, I was not  
15 suggesting that discovery, full blown discovery is re-opened.  
16 I never want to foreclose or assume that any change to  
17 contentions means that there is no discovery to be had.

18 I understand what the sentence says and I understand  
19 that your position is that it just simply means there's a new  
20 cause of action. But I don't want to foreclose, in this case,  
21 Plaintiff from making an argument that there's something else  
22 that they need.

23 And if I agree with you, and I know Hanmi's position  
24 has been all along that even if there is a change that it  
25 wouldn't require discovery, and I understand what you're

1       arguing. I just am not foreclosing it, I just simply  
2       cautioning AstraZeneca that they'd have to convince me that  
3       this ruling is something that they have -- they haven't been  
4       addressing in discovery. So I want to leave it at that.

5               As to the second point, I am, as I referenced, a  
6       little perplexed as to why at least some of these requests  
7       for admission could not have been responded to. I mentioned  
8       #104: humans are mammals. Right above that, #103, if approved  
9       for the indication sought in Hanmi's NBA, Hanmi's drug  
10      products will be administered to humans.

11             I don't get, Mr. Volen, and I'm not quite loving  
12      Hanmi's responses that they can't answer any of these. So I  
13      will encourage you to use these requests for admissions, 1  
14      through 124, as the starting point for what you can stipulate  
15      to and I'm going to hold you to a tight time frame, in light  
16      of the production of expert reports.

17             I'd like you to let AstraZeneca which, if any, of  
18      these you can agree to or would stipulate to by a week from  
19      Monday. So what is that, the 11th. So by the 11th, I don't  
20      know how much help that will give AstraZeneca, but I would  
21      want -- I want Hanmi to at least let AstraZeneca know.

22             Perhaps we won't view them as requests to admit and  
23      here's where the tweaking could come in. If for some reason  
24      Hanmi wants to qualify 103 by saying Hanmi's drug products  
25      will not be -- will be administered to humans, "at least as of

1       this approval process" because you don't want to foreclose  
2       that sometime in the future you might decide that it has some  
3       use for some other mammal or other species that's out there.  
4       Go ahead and do that.

5               If there's something in the -- the phrase or the  
6       sentence that is troubling, that a qualifier might help, add  
7       it and send it to AstraZeneca and maybe that will be good  
8       enough to keep this process moving.

9               And if you figure out that humans are not mammals,  
10       tell me. Good?

11              MR. HAUS: Your Honor, this is Bruce Haus for  
12       Plaintiff. Thank you for that clarification. The whole  
13       purpose of the -- phase was to find out exactly whether we do  
14       have an issue and I think what you just proposed will work and  
15       we will work with Hanmi's lawyers to get as much of this done  
16       as we can between now and a week from Monday.

17              THE COURT: Okay. That would be great. And if you  
18       need slight tweaking to the expert production, let me know,  
19       because I see percolating the potential -- the potential that  
20       there could be additional discovery sought based on the  
21       contention amendment, but also we have this issue of why that  
22       form was changed. I don't know that that's going affect, I  
23       can't anticipate that would affect experts necessarily.

24              But if you want to talk to me about a tweaking of  
25       the schedule a bit, I'm open to that. You folks know more

1       than me, the matter of time being of the essence.

2               So I will check in with you in a week -- I'll check  
3       in with you after the 11th to see how things look, if I  
4       haven't heard from you, how's that?

5               MR. HAUS: That's fine, Your Honor. There is one  
6       other issue that if you have a moment we'd like to address.

7               THE COURT: Sure. I have nothing else to do on  
8       Friday afternoon. Go ahead.

9               MR. HAUS: I understand that and I apologize. As  
10      you may know, Your Honor, we have a motion pending in the  
11      District Court of Maryland on a third party subpoena. We've  
12      requested documents from Hanmi's US agent back in August of  
13      last year. And essentially we've been stonewalled for about  
14      six months for getting these documents that likely would be in  
15      the control of Hanmi, but I'm not sure of that.

16              That Motion to Compel is now fully briefed -- sorry,  
17      the motion in Maryland is not fully briefed, but it will be  
18      addressed soon and we expect -- we hope to get some additional  
19      documents for that. We don't know when that will be, but that  
20      may have an impact on the schedule as well.

21              That's the only other pending discovery issue that's  
22      not yet been resolved.

23              THE COURT: I appreciate that. I am not a big fan  
24      of amending expert reports. I think that often causes more  
25      problems than it's worth, but again not knowing the import or

1 potential import of the documents that you're seeking, it's  
2 hard for me to give you specific direction.

3 So let me plant this thought. Have a chat. I would  
4 prefer certainly to have the expert reports produced sooner  
5 rather than later so that we can keep you moving and then I  
6 can field any unanticipated issues that might come up. But if  
7 you folks agree that it's -- the better course is to wait for  
8 the Maryland Court to decide and you want to set a time frame  
9 where you will hold off producing expert reports until X date,  
10 giving Maryland a chance to decide, but if they haven't, then  
11 you'll produce them with the right to seek to amend. I could  
12 certainly live with that, but I just use the -- the caveat or  
13 cautionary statement that often that's -- amending is more of  
14 a problem than it's worth.

15 But I leave that to you folks if you think that you  
16 want to produce so that you have the bulk of it in and if you  
17 need to seek to amend after you get those other documents,  
18 then we can deal with it.

19 I'm putting a lot on you to really talk about what  
20 makes sense, because you certainly should know your case and  
21 what could be out there with these documents better than I  
22 could and how important they might be to what you're  
23 producing.

24 MR. VOLEN: Your Honor, --

25 MR. HAUS: I understand, Your Honor.

1 MR. VOLEN: -- on this one two. Again this subpoena  
2 was served back in August and it's directed to a company  
3 called Carexel (phonetic) or a third party that Hanmi retained  
4 to interface with the FDA on its behalf. The third party  
5 retained its own Counsel to deal with the subpoena. We  
6 believe the subpoena simply requests documents that are  
7 probably going to be close to 100 percent duplicative of the  
8 documents that Hanmi produced in its FDA correspondence file  
9 in this case. That's been their job.

10 And contrary to Mr. Haus' insinuation, they should  
11 not stonewall AstraZeneca in responding to the subpoena from  
12 what I understand. Although AstraZeneca did not include us in  
13 the loop, in their communications with the third party, so we  
14 don't always know what's going on.

15 And I just realized, as I was checking to prepare  
16 for the call today, that although AstraZeneca supplied you  
17 with their motion papers to compel, they didn't supply you  
18 with what I understand are the opposition papers that Carexel  
19 filed in the Maryland court last week.

20 So having just seen those and skimming them myself,  
21 Carexel has a number of very significant objections to the  
22 subpoena. I do hope they're resolved, but honestly, Your  
23 Honor, I think this is all a tempest in a teapot, because  
24 whatever they might get out of Carexel is going to be  
25 duplicative of the FDA documents they already got from Hanmi.



1 THE COURT: Okay. Well then let me ask them, maybe  
2 I'm sometimes too practical. Why haven't you been able to  
3 broker, if you hired them, a resolution of this by perhaps  
4 getting a certification from the third party saying that --  
5 whatever it is -- for example: "Everything we got that we  
6 would produce to you we got from Hanmi." Hanmi can assert  
7 that there isn't anything additional or the two of you and/or  
8 do a search to call out the documents that might not have been  
9 produced.

10 Again I don't know what the universe could be, but  
11 if there was a way of shortening that issue, certainly the  
12 Maryland Judge would want to know or see a certification if  
13 that hasn't already been produced. And I don't know if that  
14 would make Astra go away.

15 MR. HAUS: That might make Astra go away, Your  
16 Honor, that would be very helpful. It's been our experience  
17 that, you know, Carexel has maintained that it's an  
18 independent company. I certainly understand that. But Mr.  
19 Volen certainly can't know what's in their files if they are  
20 that independent.

21 He seems to know and I can understand that, because  
22 Carexel is the US agent for Hanmi. So if Hanmi were to  
23 suggest that they do something of the sort you just described,  
24 it might resolve this issue much more quickly that has been --  
25 than we've been doing in Maryland right now.

1 THE COURT: You know if this issue was before me I  
2 would invite you to invite the third party to get on the phone  
3 with me or to just simply write to me in lieu of a whole  
4 Motion to Compel. I don't have jurisdiction over that fight  
5 and I don't want to step on anybody's toes.

6 So I just offer that if Hanmi is in touch with them  
7 and you can -- want to relay or, you know, I don't think that  
8 it would be inappropriate for AstraZeneca, for you to reach  
9 out and say this discussion came up and, you know, if it's so  
10 that the production would be duplicative, then just tell me  
11 that in a certification and we might go away.

12 So if you can broker that resolution, I'm sure  
13 whoever this poor Judge in Maryland is, who has no idea what  
14 you're about, would be very grateful.

15 MR. HAUS: Well, maybe we can try to get the -- Mr.  
16 Volen's firm and the firm representing Carexel together on a  
17 phone call with us and we can try to discuss the potential  
18 compromise.

19 THE COURT: That would be perfect. And you can tell  
20 them that at my suggestion. So, Mr. Volen, if you want to use  
21 me as cover. I can't order it, but that I just suggested that  
22 you reach out to them to see if there was a way of resolving  
23 this so that they don't have to go any further, although it's  
24 probably fully briefed, if I understood right, but this --  
25 this might make a -- make this issue moot.

1 MR. VOLEN: Yes. Thanks, Your Honor. We'll see if  
2 we can do anything too.

3 THE COURT: Okay. Great guys. Can I go now? Are  
4 we good?

5 MR. HAUS: Yes, Your Honor.

6 THE COURT: Okay. Have a great weekend and I will  
7 be in touch in about two weeks if I haven't heard from you  
8 folks, just to make sure that there isn't anything I need to  
9 worry about and how the schedule looks and if you're moving  
10 along, I'll just plug in another date for a conference call.

11 But I'll let you go right now, because we've got  
12 certain things percolating. I'll let you without setting up  
13 another call right now. But you know where I am if you need  
14 me.

15 MR. VOLEN: -- Your Honor.

16 UNKNOWN: -- have a great weekend.

17 UNKNOWN: Your Honor, we submitted a joint letter on  
18 January 30th and are we to be operating under that?

19 THE COURT: Yes, I would operate under that and if  
20 -- you know what, I can -- yes, I'm going to operate under  
21 that letter. I was trying to think whether I should pull it  
22 back or not, if it hasn't gotten docketed.

23 Let me enter it and if you want to tweak it, then we  
24 can always do that, but I'd rather have you at least using  
25 that as the template and then however these other issues

1 affect it, you guys can decide and then let me know if you're  
2 in agreement on tweaking it at all. Good?

3 UNKNOWN: Thanks, Your Honor.

4 MR. VOLEN: One final point, I'm sorry, I didn't get  
5 to get this in before Mr. Haus moved on to Carexel, but if the  
6 Court is permitting this -- you know, the RF -- that relate to  
7 the motion, it should be to amend to be used as a template for  
8 proposed stipulation, would we be permitted to provide  
9 AstraZeneca with a similar list of proposed stipulations.

10 THE COURT: Oh, absolutely. Absolutely. And here's  
11 why I'd rather have you talk about stipulations and then have  
12 some back and forth. You're going to have to work on  
13 stipulations at some point, which you know.

14 And if it's helpful that instead of doing the black  
15 and white, for example: I can't stipulate that all humans are  
16 mammals, for whatever reason, you want to tweak it and say  
17 just "according to the science -- scientific data that we have  
18 now, all humans are mammals", and that's something you can  
19 live with. I want you to be able to have that back and forth  
20 that you would engage in if you were coming up with some  
21 stipulations.

22 So feel free to exchange them. You'll be getting a  
23 head start. That would be great. Okay?

24 UNKNOWN: Thank you, Your Honor.

25 THE COURT: All right, guys. Good luck.

Conference

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THE COURT: Bye, bye.

(Off record at 03:32:28 p.m.)

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CERTIFICATION

I, JENNIFER WILSON, the assigned transcriber, do hereby certify the foregoing transcript of proceedings before the U.S. District Court, District of New Jersey - Trenton, on February 1, 2013, on CD, index number from 02:29:00 to 03:32:28, is prepared in full compliance with the current transcription format for Judicial Proceedings and is a true and accurate non-compressed transcript of the proceedings as recorded to the best of my knowledge and ability.

S/ Jennifer Wilson

February 5, 2013

JENNIFER WILSON AD/T #623

Date

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